

REMARKS

Claims 9-16 are pending in this application. By this Amendment, the specification and claims 9-15 are amended. Support for the amendments to the claims may be found in, for example, the specification on page 4, lines 23-26. No new matter is added.

I. Objection to the Abstract

The Office Action objects to the abstract for informalities. As indicated above, attached is an amended abstract as required. Accordingly, reconsideration and withdrawal of the objection are respectfully requested.

II. Objection to Title

The Office Action objects to the title of the invention as not descriptive, and requests a new title that is "clearly indicative of the invention to which the claims are directed." By this Amendment, the title is amended as indicated above.

III. Rejection under 35 U.S.C. §112

The Office Action rejects claims 9, 10 and 12-14 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to point out and distinctly claim the subject matter which applicants regard as the invention. Applicants respectfully traverse the rejection.

A. "phase inversion temperature"

The Office Action asserts that the phase inversion temperature is undefined and, consequently, the recitation "raised to a temperature above the phase inversion temperature" lacks clarity. To one of skill in the art, the principle of the phase inversion technique is well known. As stated in Allard, "an emulsion is prepared (introduction of water into oil) at a temperature which must be above the phase inversion temperature (PIT) of the system. Namely, the temperature at which the balance between the hydrophilic and lipophilic properties of the emulsifiers employed is attained." Allard, column 5, lines 44-49. Thus, the phrase "phase inversion temperature" is a term of art, and one of ordinary skill in the art

would be well apprised of the scope of the claims. Accordingly, reconsideration and withdrawal of this ground of the rejection are respectfully requested.

B. Claim 9 - "liposoluble phase"

The Office Action asserts that the term "liposoluble phase" is a relative term which renders the claim indefinite. By this Amendment, claim 9 is amended to replace "liposoluble phase" with "emulsion." Accordingly, reconsideration and withdrawal of this ground of the rejection are respectfully requested.

C. Claim 9 - "fatty phase"

The Office Action asserts that the recitation of "fatty phase" in claim 9 is rendered indefinite as its degree of differentiation from the term "liposoluble phase" is not clear. As discussed in the preceding paragraph, claim 9 is amended to no longer recite the term "liposoluble phase." Therefore, Applicants respectfully submit that this ground of the rejection is moot. Reconsideration and withdrawal of this ground of the rejection are requested.

D. Claim 9 - "effective"

The Office Action asserts that the term "effective" in claim 9 is a relative term which renders the claim indefinite. By this Amendment, claim 9 is amended to delete the term "effective." Accordingly, reconsideration and withdrawal of this ground of the rejection are respectfully requested.

E. Claim 10 - "step c'")

The Office Action asserts that the limitation "step c')" recited in claim 10 lacks antecedent basis. By this Amendment, claim 10 is amended to recite "further comprising a step c')." Accordingly, reconsideration and withdrawal of this ground of the rejection are respectfully requested.

F. Claim 12 - "some"

The Office Action asserts that the term "some" in claim 12 is a relative term which renders the claim indefinite. Applicants respectfully disagree.

The fact that claim language, including terms of degree, may not be precise does not automatically render the claim indefinite under 35 U.S.C. 112, second paragraph. *Seattle box Co., v Industrial Crating and Packing, Inc.*, 731 F.2d 818, 221 USPQ 568 (Fed. Cir. 1984). Acceptability of the claim language depends on whether one of ordinary skill in the art would understand what is claimed, in light of the specification. See MPEP 2173.05(b).

Based on the specification, it would be apparent to one of ordinary skill that the concentration of the resultant emulsion may be increased by decreasing the amount of aqueous phase present in the emulsion. Furthermore, the maximal amount of aqueous phase which could be withdrawn would obviously be dependent on the total amount of aqueous phase originally present. Consequently, the skilled artisan would be aware that withdrawal of "some" of the aqueous phase could be any amount less than the total amount of aqueous phase originally present, dependent on the level of concentration desired by the artisan.

As such, the use of the term "some" as recited in claim 12 is not indefinite. Reconsideration and withdrawal of the rejection are respectfully requested.

G. Claim 13 - "an additional amount of aqueous phase "

The Office Action asserts that the recitation of "an additional amount" in claim 13 is indefinite. The Office Action further asserts, "the recitation of 'additional amount of aqueous phase' is further made indefinite by requiring aqueous phase be at any temperature below the undefined phase inversion temperature." Applicants respectfully disagree.

Claim 13, as amended, recites, "The process as claimed in claim 9, wherein step e) is performed by adding additional aqueous phase that is at a temperature below the phase

inversion temperature." Step e) of claim 9 recites, "lowering the temperature of the emulsion to the phase inversion temperature."

As discussed above, acceptability of the claim language depends on whether one of ordinary skill in the art would understand what is claimed, in light of the specification. *See* MPEP 2173.05(b). As regards claim 13, the skilled artisan would be aware that according to the specification and claim, the additional amount to be added is that amount which lowers the temperature of the emulsion to the PIT, which can be monitored accordingly. In practice, the skilled artisan would monitor the overall temperature of the emulsion as additional aqueous phase is added and, upon the emulsion reaching the PIT, cease adding any further amount of aqueous phase.

As such, the use of the term "an additional amount" as recited in claim 13 is not indefinite. Reconsideration and withdrawal of the rejection are respectfully requested.

H. Claim 14 - "additional amount"

The Office Action further asserts that the recitation of "an additional amount" as used the recitation "the active principle is dissolved in an additional amount of fatty phase before being incorporated into the system" in claim 14 is indefinite. Specifically, the Office Action asserts, "Said amount is indefinite because different active principles inherently exhibit different dissolution properties in the presence of different fatty phases."

Applicants respectfully acknowledge that different active principles may exhibit differing dissolution profiles. However, the skilled artisan would be aware that the "additional amount" of fatty phase required by the claim would be that amount of fatty phase in which the liposoluble active principle of interest is dissolved.

As such, the use of the term "an additional amount" as recited in claim 14 is not indefinite. Reconsideration and withdrawal of the rejection are respectfully requested.

IV. Rejection under 35 U.S.C. §102

The Office Action rejects claims 9, 11 and 14-16 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,756,110 to Allard et al. ("Allard"). Applicants respectfully traverse the rejection.

By this Amendment, claim 9 is amended to recite, "incorporating the liposoluble active principle into the emulsion, the emulsion being at a temperature above the phase inversion temperature." Despite its asserted teachings, Allard does not teach such a feature.

The Office Action alleges that Allard teaches a method comprised of emulsifying a fatty and aqueous phase at a temperature above the PIT of the medium and then cooling the established emulsion to below the PIT. The Office Action also alleges that Allard further teaches that an inorganic nanopigment is encapsulated within the emulsion either during the initial emulsification and/or after cooling below the PIT. However, Allard does not specify that its nanopigments are introduced after the two phases are mixed to produce an emulsion and when the emulsion is at a temperature above the phase inversion temperature.

Instead, Example 1 of Allard recounts a method in which the fatty and aqueous phases were both previously heated to a temperature of 90°C (i.e., higher than the PIT); the phase containing the nanopigments was then introduced and dispersed in the fatty phase; and, only then was the aqueous phase added to the resulting dispersion and the temperature lowered to the PIT. The methods of preparation recounted in Examples 2-6 of Allard also require that both the fatty and aqueous phases are first heated to a temperature of 90°C and only then is the nanopigment introduced into the fatty phase, after which the fatty and aqueous phases are combined. Thus, none of the Examples of Allard disclose adding the nanopigments after the two phases are mixed to produce an emulsion and when the emulsion is at a temperature above the phase inversion temperature.

For at least these reasons, Allard does not anticipate claim 9. Claims 11 and 14–16 variously depend from claim 9 and, thus, also are not anticipated by Allard. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

V. Rejection under 35 U.S.C. §103

The Office Action rejects claims 9-16 under 35 U.S.C. §103(a) over Allard.

Applicants respectfully traverse the rejection.

As discussed above, Allard does not teach or suggest all the claimed features of the claim 9. As such, claim 9 would not have been rendered obvious by Allard. Claims 10-16 depend from claim 9 and, thus, also would not have been rendered obvious by Allard. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

VI. Conclusion

In view of the foregoing, it is respectfully submitted that this application is in condition for allowance. Favorable reconsideration and prompt allowance of claims 9-16 are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact the undersigned at the telephone number set forth below.

Respectfully submitted,



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Attachments:

Amended Abstract
Petition for Extension of Time

Date: May 28, 2008

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